11/24/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone 510-337-6700

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-51175

November 17, 1997

Antonio M. Cabral
765 Alta Vista Court
Galt, California 95632

WARNING LETTER

Dear Mr. Cabral:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on October 23 and 24, 1997, by Food and Drug Administration (FDA) Investigator Karen L. Robles have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On September 22, 1997, you consigned a cow (identified by USDA laboratory report number 260866) for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed penicillin in the kidney at 0.37 parts per million (ppm). The tolerance level for residues of penicillin in the edible tissues of cattle has been established at 0.05 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate record keeping system to identify the animals you purchase to establish traceability to the source of the animals.

3. You lack an adequate system to determine from the source of the animal whether the animal has been medicated, and if so, with what drug(s).

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of December 31, 1992, through July 21, 1995, your firm offered six calves found to possibly contain drug residues and two calves with illegal drug residues of gentamycin and tetracycline. As a result of those violations, an inspection was conducted of your firm on April 19, 1994. During the inspection you were warned that it is illegal to market cull cows and calves with illegal levels of antibiotics. A Warning Letter, dated May 13, 1994, was sent to you as a result of the violations found during the inspection. USDA analytical reports also reveal, during the period of July 27, 1995, through September 23, 1997, your firm offered seven cows with illegal drug residues of penicillin, sulfamethazine, and tetracycline. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify our Sacramento resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, California 95814.

Sincerely yours,

Patricia Ziobro

Patricia Ziobro
District Director
San Francisco District